Remarks

Reconsideration and withdrawal of the rejections of the claims, in view of the amendments and remarks herein, is respectfully requested. Claims 1, 5, 25 and 31 are amended. The amendments are intended to advance the application and are not intended to concede to the correctness of the Examiner's position or to prejudice the prosecution of the claims prior to amendment, which claims are present in a continuation of the present application. Claims 1-31 are now pending in this application.

Amended claims 1, 5, 25 and 31 are supported by originally-filed claims 1, 5 and 25, respectively, and page 4, lines 15-17 and 27-29, page 28, lines 22-28, Example 2 and Figure 8 in the specification.

In response to the finality of the election of species requirement, Applicant reserves the right to petition the Commissioner to review the election of species requirement. In this regard, Applicant's Representatives note that the Examiner concedes that "the examination of the original generic and subgeneric claims...was able to be completed" (page 2 of the Office Action).

A substitute Oath/Declaration is enclosed herewith, thereby addressing the objection at page 4 of the Office Action.

The Examiner rejected claims 1, 5-6, 9, 25-26, and 31 under 35 U.S.C. § 112, first paragraph, for failing to comply with the written description requirement, as support for the phrase "wherein the mutation does not alter the *in vitro* replication of the virus" allegedly was not present in the claims or specification as filed. The amendments to claims 1 and 25 render this rejection moot. However, the Examiner is respectfully referred to page 4, lines 15-17 and 27-29, and page 28, lines 22-28 of the specification as support for the phrase "wherein the mutation does not alter the *in vitro* replication of the virus."

The Examiner also rejected claims 1, 5-6, 9, 25-26, and 31 under 35 U.S.C. § 112, first paragraph, asserting that neither the claims nor the specification indicate the structural attributes shared by the members of the genus (a written description rejection). This rejection is respectfully traversed.

To provide an adequate written description for a claimed genus, the specification can provide a sufficient description of a representative number of species by an actual reduction to

practice, reduction to drawings or by a disclosure of relevant, identifying characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics. Guidelines for Examination of Patent Applications under 35 U.S.C. § 112(1) Written Description Requirement, Fed. Reg., 66, 1099 (2001). Satisfactory disclosure of a representative number of species depends on whether one skilled in the art would recognize that Applicant was in possession of the necessary common attributes or features of the elements possessed by members of the genus. Guidelines for Examination of Patent Applications under the 35 U.S.C. § 112(1) Written Description Requirement, Fed. Reg., 66, 1099 (2001).

The specification discloses that substitutions and deletions in or near the transmembrane domain of the ion channel protein gene of influenza virus can result in a mutant influenza virus which replicates *in vitro* but is attenuated *in vivo* (page 3, line 29-page 4, line 5). It is also disclosed that in influenza A virus, the transmembrane domain of the ion channel protein M2 includes residues 25-43 (page 3, line 29-page 4, line 1). Example 2 discloses that mutations in the transmembrane region of the M2 gene of influenza A virus, including substitutions and a deletion, yielded recombinant virus which replicated *in vitro* but which were attenuated *in vivo*.

Thus, Applicant has described the common structural attributes of members of the claimed genus, e.g., a recombinant influenza virus with at least one substitution or a deletion in the transmembrane domain of the influenza virus ion channel protein, and functional characteristics coupled with a known or disclosed correlation between function and structure, e.g., the presence of the substitution or the deletion does not alter the *in vitro* replication of the virus in the absence of amantadine but is associated with attenuation *in vivo*.

And as for the number of substitutions or size of deletions in the transmembrane domain in the recombinant virus (page 8 of the Office Action), the nucleotide substitutions or deletion in the transmembrane domain of the corresponding ion channel gene is such that the resulting recombinant virus can be isolated, i.e., the virus must be viable (replicates) *in vitro*. Thus, alterations in the transmembrane domain which do not yield viable virus are not within the scope of the claims.

Therefore, withdrawal of the § 112(1) rejections is respectfully requested.

Conclusion

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (612) 373-6959 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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Date November 21, 2003 By _____
Janet E. Embretson
Reg. No. 39,665

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop AF, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 21st day of November, 2003

Dawn M. Poole _____ Dawn M. Poole

Name Signature